

REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested.

Claim 21 stands rejected under 35 USC 103 as allegedly being obvious over Kross et al in view of Watson et al. Withdrawal of the rejection is in order for the reasons that follow.

At the outset, the Examiner's attention is directed to the fact that claim 21 depends from claim 18. The Examiner clearly appreciates that the method of claim 18 would not have been obvious over Kross et al in view of Watson et al as claim 18 is not subject to the rejection. For this reason alone, withdrawal of the rejection is clearly in order.

While no further comment is believed to be necessary, Applicant reminds the Examiner that the present invention relates to a method of disinfecting a dental object contaminated by *Candida*. The composition used comprises at least one chloride compound (as recited in claim 18), and at least one oxidizing agent (having the oxidation potential recited in claim 18) for the *in situ* production of chlorine during the dissolution of the composition in an aqueous solution. The composition further comprises an acid in such quantity that the composition dissolved in an aqueous solution produces a pH value of less than 6. Claim 21 defines the oxidizing agent as a hydrogen peroxosulphate compound.

Kross et al relates to:

low concentration chlorous-acid generating compositions useful for oral hygiene. The compositions are effective oral disinfectants which do not have the strong unpleasant taste of chlorine and are useful in reducing plaque.

(See Abstract – underlining added).

The disinfecting compositions of Kross et al are taught to be useful as a mouthwash, toothpaste, lozenge, chewing gum, etc. (see column 1, lines 21-23).

As pointed out in the prior response, the composition of Kross et al comprises

- a flavoring agent
- an aqueous solution containing a suitable amount of a protic acid, e.g. a carboxylic acid, and
- an amount of a metal chlorite such that the chlorite ion concentration in the form of chlorous acid is no more than 15 w/w of the total amount of chlorite ion concentration.

The protic acid can be selected from the group of citric, malic, tartaric, glycolic and mandelic acid (col. 5, lines 8 to 10). The use of polyhydroxy compounds is recommended since these can catalyze the formation of chlorine dioxide (col. 5, lines 47 to 53). Although the composition may contain a large excess of chloride ion in the form of an alkali metal salt, Applicant submits that the alkali metal salt acts only as a catalyzer (column 6, lines 15-23). The about 10 to 100 fold excess of chloride ion over total chlorite ion concentration allegedly causes the chlorite ion to decompose in an accelerated manner via the formation of chlorous acid to form chlorine dioxide (col. 6, lines 15 to 23).

Stated otherwise, Kross et al uses a metal chlorite compound for producing chlorous acid in an aqueous medium. The addition of an excess of chloride ion serves only to catalyze the decomposition of chlorite ion to form chlorine dioxide (col. 6, lines 15 to 23). The efficacy of the composition of Kross et al is based on chlorine dioxide. There is no oxidizing agent present in the composition of Kross et al with an oxidation potential that would allow the oxidation of Cl⁻ ion in solution. In contrast, in the present invention, the alkali or alkaline earth metal salt is used as a starting material for the *in-situ* production of chlorine.

The Examiner contends that Kross et al discloses an oxidation means in the form of vicinal hydroxyl groups of the alpha-hydroxy carboxylic acid (referring to column 4, line 8). Applicant submits that alpha-hydroxy carboxylic acid cannot be considered to be an oxidation means and respectfully requests that the Examiner provide support for his assertion.

In summary, it is a goal of the present invention to produce *in-situ* chlorine. In contrast, the stated aim of Kross et al is to avoid the unpleasant taste of chlorine. Kross et al, therefore, teaches away from the present invention.

Watson et al relates to cleaning and soil dispersing compositions comprising ethoxylated/propoxylated polyalkyleneamine polymers (see Abstract). Fabric laundering, dishwashing and hard-surface cleaning compositions with improved soil dispersing properties are provided. Applicant submits that it would not have been obvious to add an additional component, like a hydrogen peroxosulfate disclosed by Watson et al, to the composition of Kross et al because:

- a) the composition of Kross et al is already effective in the destruction of *Candida albicans*,
- b) Watson et al does not mention any effect in relation to *Candida albicans* and
- c) it is a declared goal of Kross to avoid the unpleasant smell of chlorine, i.e., a characteristic that is shown by the composition of the present invention..

Applicant submits that sodium peroxide is used just for bleaching purposes, not for the *in-situ* production of chlorine as in the present invention.

It is not clear from the Examiner's comments why one skilled in the art would have been motivated to combine the bleaching agent of Watson et al with the formulation of Kross et al. In the Action dated June 10, 2008, the Examiner merely states that it would have been obvious to

combine the teachings of Kross et al and Watson et al as they both teach compositions “for the purpose of oral hygiene and, for example, the cleansing of oral hygiene objects.” This comment suggests that it would have been obvious to combine any and all components of any and all such compositions – surely that cannot be the Examiner’s view. The appropriate question is why, given the teachings of the references taken as a whole, including the stated goal of Kross et al, would it have been obvious to make the combination upon which the Examiner relies. Applicant submits that, in fact, it is only with improper hindsight-based reasoning that the combination would have been made. Accordingly, reconsideration and withdrawal of the rejection are requested.

Claims 18-37 stand rejected under 35 USC 103 as allegedly being obvious over Pollock et al in view of Yoshida et al. Withdrawal of the rejection is in order for the reasons that follow.

Pollock discloses a method of treating *Candida* infections of surfaces and cavities of dentures and oral cavities. The antifungal composition used includes a humectant in a concentration from about 20% to about 80% and lytic activating agents like inorganic monovalent anions and detergents. Examples of lytic facilitators include sorbitol and glycerol (column 5, line 45). Although the humectants are not fungilytic by themselves, these humectants allegedly cause lysis of *Candida* cells in the presence of lytic activators like monovalent anions and detergents. Applicant submits that the efficacy of the composition of Pollock et al is attributable to a synergistic effect between the lytic activating agents and the lytic facilitators.

The lysis is accompanied by fungicidal death, particularly with the active fungicidal agent, sodium lauroyl sarcosinate (column 5, lines 52-55). The composition can further contain a small amount of bicarbonate ion and, optionally, thiocyanate, chloride or fluoride ion and non-ionic detergents (column 5, lines 55-59). By way of example (column 13, Example 10), a

cleaning tablet of Pollock et al comprises Sorbitol, Sodium Bicarbonate, Sodium Thiocyanate, Sodium Lauryl Sulfate, Tween 20, Potassium Monopersulfate, Sodium Borate Perhydrate, Citric Acid, Sodium Carbonate, Magnesium Stearate, Silica and Flavor.

Yoshida et al discloses a cleaning composition for an artificial denture which comprises β -1,3 glucanase, i.e., an enzyme, as an *essential* component together with one or more of suitable carriers (see Abstract).

The composition can further comprise a buffer in such an amount that the concentration of β -1,3 glucanase is at least 0.3 unit/ml and the pH ranges between 5 and 8. (See column 3, lines 4-31).

It will be clear from the foregoing that the efficacies of the compositions of Pollock et al and Yoshida et al against *Candida albicans* are based on completely different active compounds. In Pollock et al, *Candida* killing results from humectant/facilator lysis of *Candida* cells. Yoshida et al describes an enzymatic approach to *Candida* removal. Absolutely no basis would have existed for combining elements of these wholly distinct compositions as the Examiner has done.

In contrast to both Pollock et al and Yoshida et al, the present invention results from Applicant's surprising discovery that chlorine is capable of rendering harmless *Candida*, that *in situ* generation of chlorine during dissolution is particularly effective and, further, that in an acid environment it is possible to kill *Candida* within minutes. Nothing in the references, taken alone or in combination, would have suggested this approach.

Reconsideration is requested.

WOLLWAGE
Appl. No. 10/518,908
July 27, 2009

This application is submitted to be in condition for allowance and a Notice to that effect is requested. **Should the Examiner find that any issue(s) remain outstanding, he is urged to contact the undersigned by phone so that the scheduling of a interview can be discussed.**

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: Mary J. Wilson
Mary J. Wilson
Reg. No. 32,955

MJW:tat
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100